III. REMARKS

Claims 19-28 have been withdrawn because they pertain to a non-elected invention. Applicants contend that upon allowance of the invention of Group I, claims 1-18, that the invention of non-elected Group II, claims 19-28, should be rejoined with the allowed claims in accordance with MPEP § 821.04 because the claims of Group II depend upon the claims of Group I, and, therefore, incorporate all of the subject matter of at least one allowed claim.

By the present paper, the specification has been amended to properly refer to the trademark PALATINOSE™ with its generic name, isomaltulose, as supported on page 17, lines 20-22, of Applicants' English translation filed July 1, 2004 of Applicants' specification as originally filed. A substitute specification in compliance with 37 C.F.R. 1.125 is attached to incorporate the above changes, and to incorporate the change in Title per Preliminary Amendment (A), filed July 1, 2004, and to incorporate the priority claim and the foreign priority references in accordance with Amendment (B), filed June 23, 2008. The attached substitute specification contains no new matter.

Claims 1-8, 12-14 and 18 have been amended, and new claims 29-40 have been added. Specifically, claims 1-8, 12-14 and 18 have been amended to replace the term "palatinose" with the term "isomaltulose" as supported on page 17, lines 20-22, of Applicants' specification as originally filed, which has no further limiting effect on the scope of the claims. Claims 1-8, 13 and 14 have also been amended to recite "one or more components selected from the group consisting of a pharmaceutical ingredient and a carrier" as supported on page 24, line 26, to page 25, line 4, of Applicants' English translation filed July 1, 2004 of Applicants' specification as originally filed. Claims 1-3, 7 and 8 have been further amended to recite "5 g or more of isolmaltulose per 60 kg of body weight of an individual as an active ingredient" as supported by ¶¶ [0055] and [0065] of Applicants' English translation filed July 1, 2004 of Applicants' specification as originally filed. Claims

4-6, 13 and 14 have been further amended to recite "10 g or more of isolmaltulose per 60 kg of body weight of an individual as an active ingredient" as supported by ¶¶ [0056] and [0076] of Applicants' English translation filed July 1, 2004 of Applicants' specification as originally filed.

New claims 29, 31, 33, 35, 37 and 39 depend upon claims 1-6, respectively, and additionally recite "wherein the one or more components include a carrier, and the carrier is a gum" as supported by Tables 2, 6 and 10 of Applicants' disclosure as originally filed. New claims 30, 32, 34, 36, 38 and 40 depend upon claims 1-6, respectively, and additionally recite "wherein the one or more components include a pharmaceutical ingredient, and the pharmaceutical ingredient is a vitamin" as supported by Tables 3, 4, 5, 7 and 9 of Applicants' disclosure as originally filed.

The present amendment adds no new matter to the above-captioned application.

A. The Invention

The present invention pertains broadly to a reducer of blood glucose level increase, a reducer of body fat accumulation, and a food material. In accordance with an embodiment of the present invention, a reducer of blood glucose level increase is provided that includes elements recited by independent claim 1. In accordance with another embodiment of the present invention, a reducer of blood glucose level increase is provided that includes elements recited by independent claim 2. In accordance with yet another embodiment of the present invention, a reducer of blood glucose level increase is provided that includes elements recited by independent claim 3.

In accordance with another embodiment of the present invention, a reducer of body fat accumulation is provided that includes elements recited by independent claim 4. In accordance with yet another embodiment of the present invention, a reducer of body fat

accumulation is provided that includes elements recited by independent claim 5. In accordance with still another embodiment of the present invention, a reducer of body fat accumulation is provided that includes elements recited by independent claim 6.

In accordance with another embodiment of the present invention, a food material is provided that includes elements recited by independent claim 7. In accordance with yet another embodiment of the present invention, a food material is provided that includes elements recited by independent claim 8. In accordance with still another embodiment of the present invention, a food material is provided that includes elements recited by independent claim 13. In accordance with another embodiment of the present invention, a food material is provided that includes elements recited by independent claim 14. Various other embodiments, in accordance with the present invention, are recited by the dependent claims.

An advantage provided by the various embodiments of the present invention is that palatinose is employed to have beneficial effects on a individual's metabolism by, for example, reducing the level of glucose increase after ingesting a carbohydrate, and/or reducing the accumulation of fat after ingesting a carbohydrate.

B. The Rejections

Claims 1-18 stand rejected under 35 U.S.C. § 112, second paragraph, as allegedly indefinite.

Claims 1-18 stand rejected under 35 U.S.C. § 101 as allegedly failing to recite statutory subject matter.

Claims 1-18 stand rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Lina et al. (B. A. R. Lina et al., 40 FOOD AND CHEM. TOX. 1375-1381 (2002), hereafter the "Lina Article"). Claims 1-18 stand rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Bucke et al. (U.S. Patent 4,587,119, hereafter the "Bucke Patent"). Claims 1-18 also stand

rejected under 35 U.S.C. § 102(e) as allegedly anticipated by Brendel et al. (U.S. Patent Application Publication No. 2002/0192344 A1, hereafter the "Brendel Publication").

Applicants respectfully traverse the Examiner's rejections and request reconsideration of the above-captioned application for the following reasons.

C. Applicants' Arguments

In view of the present amendment, claims 1-18 and 29-40 are in compliance with 35 U.S.C. § 112. Specifically, Applicants have replaced the term "palatinose" with its equivalent, --isomaltulose--, thereby removing any uncertainty due to the use of a trademark in the claims.

i. The Section 101 Rejection

According to 35 U.S.C. § 101,

> "Whoever invents or discovers any new and useful process, machine, manufacture, composition of matter, or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title."
> 35 U.S.C. § 101.

The Examiner erroneously contends that claims 1-18 fail to recite statutory subject matter falling within the scope of 35 U.S.C. § 101 because "[t]he claimed reducer of blood glucose level increase reads upon naturally occurring honey and sugarcane..., both of which comprise sucrose and can be considered foodstuffs" (Office Action, dated March 30, 2009, at 6, lines 11-13). The Examiner's contention is incorrect for the following reasons.

First, claims 1-3 pertain to a "reducer of blood glucose level increase" that includes "5 g or more of isolmaltulose per 60 kg of body weight of an individual" and "one or more components selected from the group consisting of a pharmaceutical ingredient and a carrier." Therefore, the embodiment recited by claims 1-3 pertains to at least a man-made composition

or manufacture falling within the scope of statutory subject matter in accordance with 35 U.S.C. § 101.

Second, claims 4-6 pertain to a "reducer of body fat accumulation" that includes "10 g or more of isolmaltulose per 60 kg of body weight of an individual" and "one or more components selected from the group consisting of a pharmaceutical ingredient and a carrier." Therefore, the embodiment recited by claims 4-6 pertains to at least a man-made composition or manufacture falling within the scope of statutory subject matter in accordance with 35 U.S.C. § 101.

Third, claim 7 pertains to "food material" that includes "5 g or more of isolmaltulose per 60 kg of body weight of an individual" and "a foodstuff composed of a carbohydrate having an α-1,6-glucosyl bond ratio of from 0% to less than 50% relative to the total bonds among constituent saccharides" and "one or more components selected from the group consisting of a pharmaceutical ingredient and a carrier." Therefore, the embodiment recited by claim 7, and that of dependent claim 12, pertain to at least a man-made composition or manufacture falling within the scope of statutory subject matter in accordance with 35 U.S.C. § 101.

Fourth, claim 8 pertains to "food material" that includes "10 g or more of isolmaltulose per 60 kg of body weight of an individual" and "at least one foodstuff selected from the group consisting of sucrose, wheat flour, starch, dextrin and high fructose corn syrup" and "one or more components selected from the group consisting of a pharmaceutical ingredient and a carrier." Therefore, the embodiment recited by claim 8, and those of dependent claims 9-11, pertain to at least a man-made composition or manufacture falling within the scope of statutory subject matter in accordance with 35 U.S.C. § 101.

Fifth, claim 13 pertains to "food material" that includes "10 g or more of isolmaltulose per 60 kg of body weight of an individual" and "a foodstuff composed of a

carbohydrate having an α-1,6-glucosyl bond ratio of from 0% to less than 50% relative to the total bonds among constituent saccharides" and "one or more components selected from the group consisting of a pharmaceutical ingredient and a carrier." Therefore, the embodiment recited by claim 13, and that of dependent claim 18, pertain to at least a man-made composition or manufacture falling within the scope of statutory subject matter in accordance with 35 U.S.C. § 101.

Sixth, claim 14 pertains to "food material" that includes "10 g or more of isolmaltulose per 60 kg of body weight of an individual" and "at least one foodstuff selected from the group consisting of sucrose, wheat flour, starch, dextrin and high fructose corn syrup" and "one or more components selected from the group consisting of a pharmaceutical ingredient and a carrier." Therefore, the embodiment recited by claim 14, and those of dependent claims 15-17, pertain to at least a man-made composition or manufacture falling within the scope of statutory subject matter in accordance with 35 U.S.C. § 101.

Seventh, new claims 29-40 recited additional constituents pertaining to the man-made compositions or manufactures recited by the base claims.

For all of the above reasons, claims 1-18 and 29-40 recite statutory subject matter in compliance with 35 U.S.C. § 101.

ii. The Section 102 Rejections

Anticipation under 35 U.S.C. § 102 requires showing the presence in a single prior art reference disclosure of each and every element of the claimed invention, arranged as in the claim. Lindemann Maschinenfabrik GMBH v. American Hoist & Derrick, 221 U.S.P.Q. 481, 485 (Fed. Cir. 1984). In this case, the Examiner has failed to establish a prima facie case of anticipation against Applicants' claimed invention because neither the Lina Article, the

Bucke Patent, nor the Brendel Publication, teaches or suggests, each and every element of the claimed invention, arranged as in the claims.

iii. The Lina Article

The Lina Article pertains to a review of biological and toxicological studies of isomaltulose. The Lina Article characterizes isomaltulose as a reducing disaccharide found in honey, sugar cane juice, and in man-made products such as treacles and food-grade molasses (See Lina Article, at 1375, left col., lines 2-7). The Lina Article discloses that rises in blood glucose, fructose and insulin levels following isomaltulose ingestion are slower than those caused by sucrose because isomaltulose undergoes slower hydrolyzation in the gastrointestinal tract (Lina Article, at 1377, left col., lines 3-9). The Lina Article also discloses that rats fed a mixture of isomaltulose and sucrose over thirteen weeks did not die or exhibit behavioral changes (Lina Article, at 1377, right col., line 46, to 1378, left col., line 2).

The Lina Article, however, does not teach, or even suggest, (i) a "reducer of blood glucose level increase" that comprises "one or more components selected from the group consisting of a pharmaceutical ingredient and a carrier" as recited by independent claims 1-3, and (ii) a "reducer of body fat accumulation" that comprises "one or more components selected from the group consisting of a pharmaceutical ingredient and a carrier" as recited by independent claims 4-6, and (iii) a "food material" that comprises "one or more components selected from the group consisting of a pharmaceutical ingredient and a carrier" as recited by independent claims 7, 8, 13 and 14. Furthermore, while the Lina Article discloses feeding rats up to 8.1 g/kg body weight/day of isomaltulose (Lina Article, at 1378, left col., lines 11-15) and giving humans as little as 0.25 g/kg/dose of oral isomaltulose (Lina Article, at 1378, right col., lines 26-32), the Lina Article does not teach, or suggest, (iv) "5 g or more of

isolmaltulose per 60 kg of body weight of an individual as an active ingredient" as recited by claims 1-3, 7 and 8, and (v) "10 g or more of isolmaltulose per 60 kg of body weight of an individual as an active ingredient" as recited by claims 4-6, 13 and 14.

Furthermore, while the Lina Article discloses feeding rats a mixture of isomaltulose and sucrose for 13 weeks, the Lina Article discloses that no difference in body weight, haematology, clinical chemistry and urinalysis was observed between test rats fed a diet supplemented with an isomaltulose/sucrose mixture and control rats fed a diet supplemented with sucrose (Lina Article, at 1377, right col., line 46, to 1378, left col., line 15). Therefore, a person of ordinary skill in the art would realize that the Lina Article does not teach, or suggest, (vi) "when said reducer is ingested by an individual before or after or simultaneously with consuming a carbohydrate having an α-1,6-glucosyl bond ratio of from 0% to less than 50% relative to the total bonds among constituent saccharides, said reducer reduces an increase in blood glucose level of the individual caused by consuming said carbohydrate" as recited by claim 1, (vii) "when said reducer is ingested by an individual before or after or simultaneously with consuming at least one foodstuff selected from the group consisting of sucrose, wheat flour, starch, dextrin and high fructose corn syrup, said reducer reduces an increase in blood glucose level of the individual caused by consuming said foodstuff" as recited by claim 2, (viii) "when said reducer is ingested by an individual before or after or simultaneously with consuming food, said reducer reduces an increase in blood glucose level of the individual caused by consuming said food" as recited by claim 3, (ix) "said reducer reduces body fat accumulation" as recited by claims 4-6, 13 and 14, (x) "said food material reduces blood glucose level increase for an individual caused by consuming said foodstuff" as recited by claims 7 and 8.

The Examiner contends that the subject matter of limitations (vi) to (x) above are not given any patentable weight because they are included in "wherein" clauses that "merely

reflect the intended use and desired outcome of ingesting the isomaltulose composition" and the Examiner cites MPEP § 2111.04 in support of this proposition (Office Action, dated March 30, 2009, at 8, lines 1-10). The Examiner's contention is flawed because MPEP § 2111.04 plainly establishes that while "wherein" and "whereby" clauses, for example, may raise a question as to the limiting effect of the claimed language, the question depends on the specific facts of the case and such clauses cannot be ignored when they state a condition material to patentablility. Hoffer v. Microsoft Corp., 74 U.S.P.Q.2d 1481, 1482 (Fed. Cir. 2005).

The Federal Circuit has held that materials may be defined, in part, by various property parameters. E.I. du Pond de Nemours & Co. v. Phillips Petroleum Co., 7 U.S.P.Q.2d 1129, 1133 (Fed. Cir. 1988). In this case, the effect the invention according to claims 1-3, 7 and 8 has on blood glucose is a property of the claimed composition. Likewise, the effect the invention according to claims 4-6, 13 and 14 has on body fat accumulation is a property of the claimed composition. Therefore, the Examiner should give patentable weight to the "wherein" clauses (vi) to (x) above because these clauses define various properties of the composition that are used to define, in part, the novel composition.

The Examiner contends that the ability of isomaltulose to reduce an increase in blood glucose level and to reduce body fat accumulation is an "inherent" property of isomaltulose (Office Action, dated March 3, 2009, at 8, line 16, to 9, line 2). The Examiner's contention is incorrect for the following reasons.

First, the ability of isomaltulose to reduce the increase in blood glucose level of an individual who consumed certain types of carbohydrates, or foodstuffs, or foods, depends on exceeding a minimum dose of the isomaltulose as described in ¶¶ [0055] and [0065] of Applicants' English translation filed July 1, 2004 of Applicants' specification as originally filed. Therefore, not all compositions containing isomaltulose possess the property

pertaining to "reduc[ing] an increase in blood glucose level of the individual" as recited in claims 1-3, 7 and 8. Likewise, the ability of isomaltulose to reduce body fat accumulation in an individual who consumed certain types of carbohydrates, or foodstuffs, or foods, depends on exceeding a higher minimum dose of the isomaltulose, as described in ¶¶ [0056] and [0076] of Applicants' English translation filed July 1, 2004 of Applicants' specification as originally filed, than the minimum dose required to have an effect on blood glucose levels following ingestion of the certain types of carbohydrates, foodstuffs or foods. Therefore, not all compositions containing isomaltulose possess the property pertaining to "reduc[ing] body fat accumulation" as recited in claims 4-6, 13 and 14.

Second, the Federal Circuit has held that a reference may inherently teach subject matter not explicitly disclosed by the reference when the disclosure is sufficient to show that the implicit subject matter is the natural result flowing from the explicitly disclosed subject matter. Continental Can Co. USA Inc. v. Monsanto Co., 20 U.S.P.Q.2d 1746, 1749 (Fed. Cir. 1991). However, inherency cannot be established by mere probabilities or possibilities, and the mere fact that a certain thing may result from a given set of circumstances is insufficient. Id. The Federal Circuit has ruled that inherency is a question of fact. In re Napier, 34 U.S.P.Q.2d 1782, 1784 (Fed. Cir. 1995).

In this case, the Lina Article reports that, for rats, ingestion of up to 8.1 g/kg body weight/day of isomaltulose in a mixture with sucrose did not affect body fat accumulation with respect to controls (Lina Article, at 1377, right col., line 46, to 1378, left col., line 15). The Lina Article does not teach, or suggest, that ingestion of isomaltulose in combination with a carbohydrate having an α-1,6-glucosyl bond ratio of from 0% to less than 50% relative to the total bonds among constituent saccharides, or with at least one foodstuff selected from the group consisting of sucrose, wheat flour, starch, dextrin and high fructose corn syrup, or with food, results in the reduction in fat accumulation from ingesting these substances. On

the contrary, the Lina Article discloses that ingesting isomaltulose in combination with sucrose does not affect fat accumulation.

With respect to the affect of isomaltulose on blood glucose levels when ingested with a carbohydrate having an α-1,6-glucosyl bond ratio of from 0% to less than 50% relative to the total bonds among constituent saccharides, sucrose, wheat flour, starch, dextrin, high fructose corn syrup, or food, the Lina Article generally discloses that no differences in "clinical chemistry" as noted between control rats (sucrose only supplemented diet) and test rats (diet supplemented with isomaltulose and sucrose mixture), (Lina Article, at 1377, right col., line 46, to 1378, left col., line 7). Therefore, the Lina Article does not provide a sufficient disclosure from which a person of ordinary skill in the art may conclude that the blood glucose increase reducing property of the claimed invention may be inferred as "inherent."

For all of the above reasons, the "wherein" clauses (vi) to (x) of Applicants' claims should be construed as limitations material to patentability, and that these limitations are neither "inherent" to all isomaltulose containing compositions nor "inherent" to the subject matter disclosed by the Lina Article.

The Lina Article also fails to teach, or suggest, (xi) "the one or more components include a carrier, and the carrier is a gum" as recited by claims 29, 31, 33, 35, 37 and 39, and (xii) "the one or more components include a pharmaceutical ingredient, and the pharmaceutical ingredient is a vitamin" as recited by claims 30, 32, 34, 36, 38 and 40.

For all of the above reasons, the Lina Article fails to anticipate the subject matter recited by claims 1-18 and 29-40 of the above-captioned application.

iv. The Bucke Patent

The Bucke Patent discloses a "method of reducing dental plaque formation with products for human or animal consumption using isomaltulose sucrose substitute," wherein isomaltulose is used as a whole or partial replacement for sucrose in products for human or animal consumption (See Abstract of the Bucke Patent). The Bucke Patent discloses various products, such as toffee humbugs, shortcake biscuits, marzipan, toffee, meringues, pudding, sponge cakes, canned fruits, plum jam, toothpaste, chewing gum, and lemonade that contain isomaltulose (Bucke Patent, col. 6, line 49, to col. 12, line 11). The Bucke Patent discloses that the plum jam includes isomaltulose and sucrose (Bucke Patent, Example 11, col. 10, line 61, to col. 11, line 12).

The Bucke Patent does not teach, or suggest, (i) a "reducer of blood glucose level increase" that comprises "one or more components selected from the group consisting of a pharmaceutical ingredient and a carrier" as recited by independent claims 1-3, and (ii) a "reducer of body fat accumulation" that comprises "one or more components selected from the group consisting of a pharmaceutical ingredient and a carrier" as recited by independent claims 4-6, and (iii) a "food material" that comprises "one or more components selected from the group consisting of a pharmaceutical ingredient and a carrier" as recited by independent claims 7, 8, 13 and 14. The Bucke Patent also does not teach, or suggest, (iv) "5 g or more of isolmaltulose per 60 kg of body weight of an individual as an active ingredient" as recited by claims 1-3, 7 and 8, and (v) "10 g or more of isolmaltulose per 60 kg of body weight of an individual as an active ingredient" as recited by claims 4-6, 13 and 14.

The Bucke Patent also does not teach, or suggest, (vi) "when said reducer is ingested by an individual before or after or simultaneously with consuming a carbohydrate having an α-1,6-glucosyl bond ratio of from 0% to less than 50% relative to the total bonds among constituent saccharides, said reducer reduces an increase in blood glucose level of the

individual caused by consuming said carbohydrate" as recited by claim 1, (vii) "when said reducer is ingested by an individual before or after or simultaneously with consuming at least one foodstuff selected from the group consisting of sucrose, wheat flour, starch, dextrin and high fructose corn syrup, said reducer reduces an increase in blood glucose level of the individual caused by consuming said foodstuff" as recited by claim 2, (viii) "when said reducer is ingested by an individual before or after or simultaneously with consuming food, said reducer reduces an increase in blood glucose level of the individual caused by consuming said food" as recited by claim 3, (ix) "said reducer reduces body fat accumulation" as recited by claims 4-6, 13 and 14, (x) "said food material reduces blood glucose level increase for an individual caused by consuming said foodstuff" as recited by claims 7 and 8.

The Examiner contends that the subject matter of limitations (vi) to (x) above are not given any patentable weight because they are included in "wherein" clauses that "merely reflect the intended use and desired outcome of ingesting the isomaltulose composition" and the Examiner cites MPEP § 2111.04 in support of this proposition (Office Action, dated March 30, 2009, at 9, lines 12-21). The Examiner's contention is flawed because MPEP § 2111.04 plainly establishes that while "wherein" and "whereby" clauses, for example, may raise a question as to the limiting effect of the claimed language, the question depends on the specific facts of the case and such clauses cannot be ignored when they state a condition material to patentablility. Hoffer v. Microsoft Corp., 74 U.S.P.Q.2d 1481, 1482 (Fed. Cir. 2005).

The Federal Circuit has held that materials may be defined, in part, by various property parameters. E.I. du Pond de Nemours & Co. v. Phillips Petroleum Co., 7 U.S.P.Q.2d 1129, 1133 (Fed. Cir. 1988). In this case, the effect the invention according to claims 1-3, 7 and 8 has on blood glucose is a property of the claimed composition. Likewise, the effect the

invention according to claims 4-6, 13 and 14 has on body fat accumulation is a property of the claimed composition. Therefore, the Examiner should give patentable weight to the "wherein" clauses (vi) to (x) above because these clauses define various properties of the composition that are used to define, in part, the novel composition.

The Burke Patent also does not teach, or suggest, (xi) "the one or more components include a carrier, and the carrier is a gum" as recited by claims 29, 31, 33, 35, 37 and 39, and (xii) "the one or more components include a pharmaceutical ingredient, and the pharmaceutical ingredient is a vitamin" as recited by claims 30, 32, 34, 36, 38 and 40.

For all of the above reasons, the Burke Patent fails to anticipate the subject matter recited by claims 1-18 and 29-40 of the above-captioned application.

v. The Brendel Publication

The Brendel Publication discloses a "process for preparing a low-calorie food," which involves the step consisting of replacing all or part of the high-calorie substances of the food with an effective quantity, in terms of the reduction of the calorific value, of branched maltodextrins having between 15 and 35% of 1→6 glucoside linkages, a reducing sugar content less than 20%, a polymolecularity index of less than 5 and a number-average molecular mass Mn at most equal to 4500 g/mol (See Abstract of the Brendel Publication). The Brendel Publication discloses how to make low-calorie biscuits, cereal bars, fizzy soft drinks, and bread (Brendel Publication, ¶¶ [0036] to [0113]). The Brendel Publication further discloses that the branched maltodextrins may be simultaneously present with 0.5 to 98% by weight, and preferably 5 to 98% by weight, relative to the total weight of the food, of at least one sugar selected from the group consisting of xylose, fructose, glucose, polydextrose, sucrose, maltose, lactose, isomaltose, isomaltooligosacccharides, isomaltulose, glucose

syrups, high-fructose glucose syrups, maltodextrins, fructooligosaccharides and galactooligosaccharides (Brendel Publication, ¶ [0026]).

The Brendel Publication does not teach, or suggest, (i) a "reducer of blood glucose level increase" that comprises "one or more components selected from the group consisting of a pharmaceutical ingredient and a carrier" as recited by independent claims 1-3, and (ii) a "reducer of body fat accumulation" that comprises "one or more components selected from the group consisting of a pharmaceutical ingredient and a carrier" as recited by independent claims 4-6, and (iii) a "food material" that comprises "one or more components selected from the group consisting of a pharmaceutical ingredient and a carrier" as recited by independent claims 7, 8, 13 and 14. The Brendel Publication also does not teach, or suggest, (iv) "5 g or more of isolmaltulose per 60 kg of body weight of an individual as an active ingredient" as recited by claims 1-3, 7 and 8, and (v) "10 g or more of isolmaltulose per 60 kg of body weight of an individual as an active ingredient" as recited by claims 4-6, 13 and 14.

The Brendel Publication also does not teach, or suggest, (vi) "when said reducer is ingested by an individual before or after or simultaneously with consuming a carbohydrate having an α-1,6-glucosyl bond ratio of from 0% to less than 50% relative to the total bonds among constituent saccharides, said reducer reduces an increase in blood glucose level of the individual caused by consuming said carbohydrate" as recited by claim 1, (vii) "when said reducer is ingested by an individual before or after or simultaneously with consuming at least one foodstuff selected from the group consisting of sucrose, wheat flour, starch, dextrin and high fructose corn syrup, said reducer reduces an increase in blood glucose level of the individual caused by consuming said foodstuff" as recited by claim 2, (viii) "when said reducer is ingested by an individual before or after or simultaneously with consuming food, said reducer reduces an increase in blood glucose level of the individual caused by consuming said food" as recited by claim 3, (ix) "said reducer reduces body fat

accumulation" as recited by claims 4-6, 13 and 14, (x) "said food material reduces blood glucose level increase for an individual caused by consuming said foodstuff" as recited by claims 7 and 8.

The Examiner contends that the subject matter of limitations (vi) to (x) above are not given any patentable weight because they are included in "wherein" clauses that "merely reflect the intended use and desired outcome of ingesting the isomaltulose composition" and the Examiner cites MPEP § 2111.04 in support of this proposition (Office Action, dated March 30, 2009, at 10, line 20, to 11, line 8). The Examiner's contention is flawed because MPEP § 2111.04 plainly establishes that while "wherein" and "whereby" clauses, for example, may raise a question as to the limiting effect of the claimed language, the question depends on the specific facts of the case and such clauses cannot be ignored when they state a condition material to patentablility. Hoffer v. Microsoft Corp., 74 U.S.P.Q.2d 1481, 1482 (Fed. Cir. 2005).

The Federal Circuit has held that materials may be defined, in part, by various property parameters. E.I. du Pond de Nemours & Co. v. Phillips Petroleum Co., 7 U.S.P.Q.2d 1129, 1133 (Fed. Cir. 1988). In this case, the effect the invention according to claims 1-3, 7 and 8 has on blood glucose is a property of the claimed composition. Likewise, the effect the invention according to claims 4-6, 13 and 14 has on body fat accumulation is a property of the claimed composition. Therefore, the Examiner should give patentable weight to the "wherein" clauses (vi) to (x) above because these clauses define various properties of the composition that are used to define, in part, the novel composition.

The Brendel Publication also does not teach, or suggest, (xi) "the one or more components include a carrier, and the carrier is a gum" as recited by claims 29, 31, 33, 35, 37 and 39, and (xii) "the one or more components include a pharmaceutical ingredient, and the pharmaceutical ingredient is a vitamin" as recited by claims 30, 32, 34, 36, 38 and 40.

For all of the above reasons, the Brendel Publication fails to anticipate the subject matter recited by claims 1-18 and 29-40 of the above-captioned application.

vi. Additional Comments Regarding the Present Invention and Unexpected Results

Although the Examiner has not evinced any rejection against the claimed invention under 35 U.S.C. § 103, Applicants point out that the present invention provides unexpected results over what is commonly known in the art. The Federal Circuit has held that the common sense of those skilled in the art may demonstrate why some combinations are obvious and others are not. Leapfrog Enterprises, Inc. v. Fisher-Price, Inc., 485 F.3d 1157, 1161 (Fed. Cir. 2007). Furthermore, when an applicant adduces specific data demonstrating substantially improved results, and states that the results are unexpected, then in the absence of evidence to the contrary, applicant has established unexpected results sufficient to prove the invention is nonobvious. In re Soni, 34 U.S.P.Q.2d 1684, 1687-88 (Fed. Cir. 1995). The invention need only be compared to the closest prior art, In re Johnson, 223 U.S.P.Q. 1260, 1264 (Fed. Cir. 1984), however, it is acceptable to compare the invention to subject matter that is closer to the invention than the closest prior art. Ex parte Humber, 217 U.S.P.Q. 265, 266 (Bd. Pat. App. & Inter. 1981).

The present invention is based on the discovery of unknown properties pertaining to a palatinose-containing composition that includes "5 g or more of isolmaltulose per 60 kg of body weight of an individual as an active ingredient" and "10 g or more of isolmaltulose per 60 kg of body weight of an individual as an active ingredient." Novel properties of such palatinose-containing compositions include that palatinose reduces the blood glucose level increase caused by ingesting glucose, sucrose, and the like, when palatinose content is "5 g or more of isolmaltulose per 60 kg of body weight of an individual" and palatinose reduces

body fat accumulation caused by ingesting glucose, sucrose and the like, when palatinose content is "10 g or more of isolmaltulose per 60 kg of body weight of an individual as an active ingredient." Furthermore, palatinose reduces the blood glucose level increase caused by ingesting carbohydrates other than palatinose and palatinose reduces the body fat accumulation caused by ingesting carbohydrates other than palatinose.

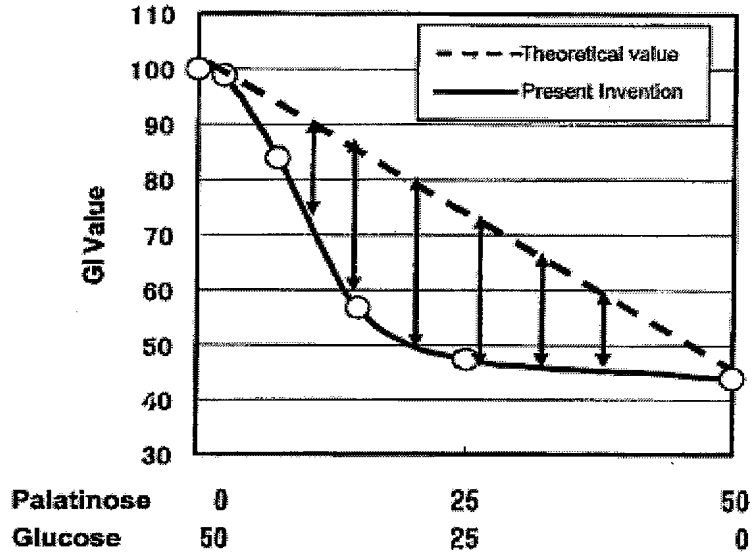
Specifically, the present invention provides a distinctive and wholly unexpected effect in that palatinose, by itself, reduces blood glucose level increase otherwise caused by the ingestion of at least one carbohydrate selected from the group consisting of maltose, sucrose, high fructose corn syrup, glucose, starch, dextrin, and branched dextrin (hereafter, collectively referred to as "maltose and the like"). Applicants explain, as follows, how it is that the present invention encompasses a "food material" and a "reducer of blood glucose level increase" in accordance with the present invention.

As is known, palatinose has a Glycemic Index (GI) of 44 and exhibits a gentler blood glucose level increase than when glucose itself is ingested (See, e.g., "Exhibit C," at 81, left col., lines 1-18, of record). GI is a value expressed relative to 100, which corresponds to the area under the curve for blood glucose level increase by glucose (See, e.g., Figure 4 and ¶ [0064] of Applicants' disclosure as originally filed, and webpage titled "About Glycemic Index," http://www.glycemicindex.com/aboutGIprint.htm, downloaded September 23, 2008, 2 pages, labeled as "Exhibit E," of record).

When palatinose is ingested substantially simultaneously with glucose, the blood glucose level increase resulting from ingestion of these carbohydrates would be expected to yield a weighted average of the blood glucose level increase due to ingestion of glucose alone and of the blood glucose level increase due to ingestion of palatinose alone. This theoretical expected rise in blood glucose level is denoted by the dashed line (--) shown in Figure A

below. Figure A is based, in part, on original Figure 4 of the above-captioned application (See also Applicant's specification as originally filed, at ¶ [0064]).

Fig. A. Relationship between GI value and palatinose ingestion amount



Ingestion amount (g) of palatinose and glucose for an ingested carbohydrate weight of 50 g.

As shown in Figure A above, when palatinose is actually ingested substantially simultaneously with glucose, the corresponding GI value curve (i.e., the solid curve in Figure A) diverges considerably from the theoretically predicted curve (i.e., the dashed line) determined from the weighted average of glucose level increase for glucose ingested alone and palatinose ingested alone. In other words, palatinose reduces the blood glucose level increase caused by glucose ingestion, as observed in Figure A, because GI value has dropped from the theoretical curve by the amount indicated by the vertical arrows. The conclusion is, therefore, that palatinose by itself has the function of a "reducer of blood glucose level increase" because it reduces the blood glucose level increase following ingestion of glucose when ingested substantially simultaneously with glucose.

As would be immediately appreciated by a person of ordinary skill in the art, the present invention achieves an unexpected effect that wholly overturns conventional

knowledge, and that provides the novel application of a "reducer of blood glucose level" wherein palatinose, by itself, reduces blood glucose level increase due to ingestion of maltose and the like when ingested substantially simultaneously with maltose and the like. Thus, the present invention provides an unexpected "reducer of blood glucose level increase" and a "foodstuff" that diminishes the blood glucose level increase otherwise expected to be observed when maltose and the like is ingested with palatinose.

For all of the above reasons, the Lina Article, the Burke Patent and the Brendel Publication, either alone or in combination, cannot sustain a prima facie case of obviousness against Applicants' claimed invention.

III. CONCLUSION

In view of the present amendment, claims 1-18 and 29-40 are in compliance with 35 U.S.C. § 112, and recite statutory subject matter in compliance with 35 U.S.C. § 101. The Examiner has failed to establish a prima facie case of anticipation against independent claims 1-8, 13 and 14 of the above-captioned application because neither the Lina Article, the Burke Patent nor the Brendel Publication teaches, or suggests, each and every limitation recited by these claims. Furthermore, neither the Lina Article, the Burke Patent nor the Brendel Publication teaches, or suggests, the subject matter of new claims 29-40.

For all of the above reasons, claims 1-18 and 29-40 are in condition for allowance, and a prompt notice of allowance is earnestly solicited.

Questions are welcomed by the below-signed attorney for Applicants.

Respectfully submitted,

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